K130220

5. Traditional 510(k) Summary

JUL 2 2 2013

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

807.92(a)(1) **Submitter Information:**	Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 FDA Registration #: 1067162 Owner Operator #: 9052354
Official Correspondent:	James M. Mewborne Manager of Regulatory Affairs Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 ext. 101 Email: jmewborne@rhythmlink.com
Summary Date:	January 22, 2013
807.92(a)(2) **Device Identification:**	**Proprietary Device Name:** MR Conditional PressOn™ Electrode (Trade name has not been finalized at this time) **Generic Device Name:** MR Conditional PressOn Electrode **Regulatory Class:** Class II **Classification Name:** 21 CFR §882.1350, Neurological Electrode **Product Code:** GXZ
807.92(a)(3) **Predicate Device(s):**	**K103103** Persyst PressOn™ Electrodes **K121347** Rhythmlink PressOn™ Electrode

807.92 (a)(4) **Device Description:**	The design of the Rhythmlink Disposable MR Conditional PressOn electrode is identical to the existing PressOn electrodes used to record neurological activity during electroencephalograph (EEG) and evoked potential (EP) procedures. The device consists of a disk shaped electrode with three sets of flat tynes or micro needles made from Nitinol. The Electrode is permanently attached to a leadwire which is 10cm (100mm) in length. An accessory cable is supplied to attach to the 10cm electrode leadwire to create a 1.0, 1.5, 2.0 or 2.5 meter traditional lengths during the Monitoring procedure. This accessory cable is labeled "MR Unsafe" and is NOT intended to be in the MR environment at any time. A significantly shorter lead wire of 10cm is permanently attached to the electrode and reduces the effects of matching the electrode leadwire length to the wave length of the RF component. This condition reduces the probability of matching the RF wave length to the leadwire length and reduces the likely hood of an increase in the heating effect. This will enable users to leave the electrodes in place during magnetic resonance imaging (MRI) procedures.
807.92(a)(5) **Intended Use / Indications for Use:**	The MR Conditional PressOn™ Electrode is intended for use in the recording of the Electroencephalogram (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is provided sterile for Single Patient Use Only and may remain on the patient in a MRI environment under specific conditions.
807.92(a)(6) **Technological Characteristics**	The main source of heating within the magnetic resonant imaging comes from the matching of the RF (radio frequency) wave length to the length of the electrode's leadwire. The reduction of the proposed device's leadwire length permanently attached to the electrode is the only physical change from the predicate device. This reduction in the cable length is to reduce the likely hood of heating effect from the RF component. The other issue is the torque produced by the magnetic field in the MR environment. The materials used in the PressOn EEG Electrode are minimally affected by the magnetic field and the reduced lead length has shown a minimal heating effect from the radio frequency "E" field. The manufacturing processes, materials and the sterility process are identical to the predicate device [K121347 and K103103], the Persyst PressOn Electrodes.
807.92(b)(1)	In summary even though the manufacturing processes are identical to those of the predicate devices bench tests were performed to verify and

Summary of Non-Clinical Tests	validate no changes had occurred and the performance remained the same as the predicate devices. There have been no design changes to the MR Conditional PressOn Electrodes other than the length of the leadwire permanently connected to the electrode. These tests consisted of the following tests; ➢ Pull Tests of the leadwire to the electrodes' connection. ➢ Resistance testing of the completed assembly Bench Testing did not raise any additional questions of safety and efficacy.
807.92(b)(2) **Clinical Tests**	In summary the clinical testing was conducted in two phases. Phase one was to determine which electrode and modality would be the worst case configuration. This was completed by using the SIMCAD X validated software with FDTD (Finite-Difference Time-Domain) modeling. The simulation plan consisted of three different electrode types; ➢ Cup Electrodes ➢ WEBB Electrodes ➢ PressOn™ Electrode The simulation testing showed the PressOn™ electrode to be the worst case configuration of the three types. All the simulation data was taken and then compared to the actual MRI testing using the same field strengths of 1.5T and 3.0T and 68 MHZ and 128MHZ respectfully. The second phase was to perform actual MRI physical testing for real world application. The physical testing also included Torque and Artifact testing and measuring.
807.92(b)(3) **Clinical Summary**	Once both the bench testing and simulation testing were completed the MR Conditional PressOn electrodes were subjected to real time MRI testing. These physical testing was completed using the known worst case configuration from the three types. (Cups, WEBBs and PressOn) The PressOn Electrode was found to be the worst case electrode. The bench testing confirmed that the materials used and the current manufacturing processes being used are the same and did not raise any additional questions of safety or efficacy. The simulation testing and the real time MRI testing were shown to be the same. Our test results were then compared to the IEC 60601-1-1 §11.1.2 – Temperature for Applied Parts, stated that the maximum temperature is not to exceed 43C^0 at any time. The temperatures in both the simulations and the real time tests only indicated a raise of 0.4C^0 at the area the electrodes are attached to the skin as measured directly under the electrode. The simulation indicated that the "Z" axis with two electrodes is the worst case in the "E" field which created the highest SAR

	and temperature. Additional simulations and testing were completed to show the results of the complete leadwire (10cm) within the E filed. In summary all testing indicated that the proposed MR Conditional PressOn Electrodes performed as expected and did not raise any additional questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 22, 2013

Rhythmlink International, LLC
c/o Mr. James M. Mewborne
1140 First Street, South
Columbia, SC 29209

Re: K130220
Trade/Device Name: MR Conditional PressOn Electrode
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: June 3, 2013
Received: June 5, 2013

Dear Mr. Mewborne

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130220

Device Name: MR Conditional PressOn™ Electrode

Indications For Use:

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Prescription Use x AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.07.22 15:58:30 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K130220